TEXAS HIV MEDICATION PROGRAM
REQUESTS TO CHANGE STATE HIV MEDICATION FORMULARY

PURPOSE

To set out the specific steps for processing requests for additions or deletions to the Texas HIV Medication Program's (the Program) HIV medication formulary.

AUTHORITY

The Texas Administrative Code, Title 25 §98.104, Medication Coverage, (a) states, "The medications provided under the Texas HIV Medication Program, and the specific eligibility criteria for them shall be determined by the commissioner of health, considering the recommendations of the HIV Medication Advisory Committee." US Department of Health and Human Services, Health Resources and Services Administration Program Policy 97-04, states AIDS Drug Assistance Program (ADAP) funds awarded under Titles I or II of the Comprehensive AIDS Resources Emergency (CARE) Act may only be used to purchase FDA-approved medications and the devices needed to administer them.

Questions regarding this policy should be directed to the Bureau Chief of HIV and STD Prevention, the Clinical Resources Division Director, or the Program Administrator of the Texas HIV Medication Program.

HOW TO REQUEST

All persons or organizations (requestors) wishing to request a change to the HIV medication formulary must do so in writing. The change may be in the form of an addition or deletion to the formulary. All medications must be FDA approved prior to requesting the medication be added to the formulary. Written requests should be submitted to the Program Administrator, Texas HIV Medication Program, Texas Department of Health, 1100 W. 49th, Austin, Texas, 78756-3199. All persons making written requests for formulary additions will receive a letter acknowledging the receipt of the request from the Program Administrator.

PROCESSING PUBLIC REQUESTS

All publicly-generated written formulary change requests received by the Program Administrator will be presented at the next scheduled meeting of the Texas HIV Medication Advisory Committee (the Committee). At that time, the Committee will review the formulary change request(s) and determine if the request(s) will be included on the agenda for the following meeting. The requestor who submitted the formulary

change request may be contacted by the Program staff, at the Committee's request, to obtain additional information.

Special Exceptions for HIV-Related Medications

At the discretion of the Program Administrator, in concurrence with the Director of the Clinical Resources Division (Division Director) and the Bureau Chief of HIV and STD Prevention (Bureau Chief), any publicly generated written request for new FDA-approved medications to treat HIV infection to be added to the formulary may be automatically included on the agenda for consideration at the next scheduled meeting of the Committee.

Information Packets

The Program will send each of the Committee members a packet containing a copy of the original written request and any additional information on all FDA approved medications listed on the agenda to be discussed at the next Committee meeting. Failure of the requestor to provide the appropriate information to the Committee will result in the medication being removed from the meeting agenda.

Presentations

The Committee reserves the right to table their decision regarding adding a medication and to ask the requestor to present additional information about the medication to the Committee at the next meeting. If additional information is necessary and the requestor is unable to attend, the Committee may select a Committee member to present the information or may elect to have a colleague familiar with the requested medication make the presentation.

Advisory Committee Recommendations

The Committee should reach a conclusion on all public requests to add or delete a medication from the formulary. The Committee's disposition shall take the form of a recommendation. Only the Commissioner of Health (the Commissioner), with input from the Bureau Chief, has the authority to grant a change to the formulary, defined as either the addition of a new medication or the deletion of an existing medication. The Committee, after reviewing and discussing the information pertaining to the medication, will make its recommendation(s) to the Program. The Committee may:

- recommend the addition of a medication,
- recommend the deletion of a medication, or
- choose to not recommend the addition or deletion of a medication.

Should the Committee choose to not recommend the addition or deletion of a medication, the Committee may:

- make a final disposition of the request, or

- table the request and direct the Program Administrator to gather additional information on the medication and resubmit the request at the following meeting of the Committee.

The Committee's final recommendation to add or delete a medication will be routed by the Program Administrator to the Commissioner for action.

Processing Committee Recommendations

After receiving a recommendation to add or delete an HIV medication from the Committee, the Program Administrator must complete HIV/STD Form No. 700.001-A. The Program Administrator will route the recommendation in memorandum form along with form 700.001-A to the Commissioner of Health for approval. The memorandum must be directed from the Program Administrator; through the Division Director; through the Bureau Chief; through the Associate Commissioner for Disease Control and Prevention; through the Deputy Commissioner for Programs; to the Commissioner.

The Commissioner will sign form 700.001-A conferring approval or rejecting the request and return the form.

PROCESSING BUREAU REQUESTS

Only the Bureau Chief, or the Program Administrator in concurrence with the Division Director and the Bureau Chief, may request a change to the HIV medication formulary without first seeking the recommendation of the Committee. Bureau requests of this type shall be based upon budget necessity. Completion of form 700.001-A shall serve as the official request and shall indicate that the Committee was not consulted. The Program Administrator will route the request in memorandum form along with form 700.001-A to the Commissioner for approval. The memorandum must be directed from the Program Administrator; through Division Director and the Bureau Chief; through the Associate Commissioner for Disease Control and Prevention; through the Deputy Commissioner for Programs; to the Commissioner.

The Commissioner will sign form 700.001-A conferring approval or rejecting the request and return the form.

Variations of Existing Formulary Medications

New formulations, strengths, or packaging variations for medications currently available on the Program formulary shall be addressed by the Program on a case-by-case basis. At the discretion of the Program Administrator, in concurrence with the Division Director and the Bureau Chief, the Program may:

- automatically add the new version of the medication to the Program formulary should the Program determine such inclusion to have either a neutral or

beneficial impact to the Program budget, without requiring the Commissioner's approval, or

- place the variant medication on the agenda of the next scheduled Committee meeting for discussion should the Program have concerns of any sort regarding the formulation, packaging, or increased cost of the new version of said medication.

If the new version of the formulary medication is presented before the Committee for discussion, the Committee may:

- recommend the addition of the new version of a formulary medication, or
- choose to not recommend the addition of the new medication to the Program formulary.

Should the Committee choose to not recommend the addition of a new version of the formulary medication, the Committee may:

- make a final disposition of the request, or
- table the request and direct the Program Administrator to gather any additional information deemed necessary by the Committee regarding the new variation of the formulary medication, and resubmit the request at the following meeting of the Committee.

The Committee's final recommendation to add a new version of a medication already on the Program formulary will be automatically added to the formulary by the Program Administrator in concurrence with the Division Director & Bureau Chief.

NOTIFICATION OF DISPOSITION

The Division Director will notify the Program Administrator of the final disposition. The Program Administrator shall also notify the public requestor of the final disposition if the original request was publicly generated. The Program shall immediately notify the Committee of the final disposition if the request was Bureau generated.

The Program will notify clients, providers, and HIV/STD contractors of the addition or deletion of a medication through any combination of the following methods:

- by mail,
- by fax,
- by publication as a notice in the *Texas Register*,
- through the media, and
- electronically (via email or the internet if possible).

PRODUCTION AND/OR DISTRIBUTION PROBLEMS WITH EXISTING FORMULARY MEDICATIONS

Should the Program experience problems with obtaining a particular formulary medication due to manufacturing or distribution interruptions from the medication's

manufacturer, the Program will call such problems to the attention of the Committee if the situation occurs for an extended length of time or in repeated intervals over a given period. Shortages in medication stock can pose serious barriers to client therapy and adherence; should the Program be unable to consistently guarantee the availability of a given medication for eligible Program clients, the Committee reserves the right to make recommendations to delete a medication from the Program formulary or modify the requirements for obtaining that medication from the Program.

DATE OF LAST REVIEW:

November 13, 2002 Converted format from WordPerfect to Word.

REVISIONS

Page 1, line14	added "the Clinical Resources Division Director," after "Bureau Chief of HIV and STD Prevention," and deleted the word "to" after "or" and before "the Program Administrator of the Texas HIV Medication Program."
Page 1, line 18	changed the word "drug" to "medication" before "must be FDA approved"
Page 1, line 19	added "the medication be added to the formulary" and deleted "any formulary additions" after "must be FDA approved prior to requesting"
Page 1, line 22	deleted "and a letter of disposition" after "a letter acknowledging the receipt of the request"
Page 1, line 24	deleted "since adjournment of the last meeting of the Texas HIV Medication Advisory Committee (the Committee)" after "requests received by the Program Administrator"
Page 1, lines 24-25	deleted "to the Committee" after "will be presented" and added "of the Texas HIV Medication Advisory Committee (the Committee)" after the word "meeting"
Page 1, line 26	changed "requests" to "request(s)"; deleted "which" and added "if the"
Page 1, line 28	deleted "Committee" and replaced it with "Program" after "may be contacted by the"
Page 1, line 28	added ", at the Committee's request," after the word "staff"
Page 2, line 4	deleted "antiretroviral" after "request for new FDA-approved"
Page 2, line 1	deleted "Antiretroviral" and replaced with "HIV-Related" after "Exceptions for" and before "Medications"
Page 2, line 7	added "a copy of" after the word "containing" and added "written" before the word "request"
Page 2, line 8-9	deleted "following" and added "next Committee" before the word "meeting"
Page 2, lines 10	deleted "removal of the listed drug" and added "medication being removed" after "will result in the"
Page 2, line 12	deleted "the" and added "a" before the word "medication"
Page 2, line 13	deleted "following" and added "next" before the word "meeting"

Page 2, lines 20-21	added “defined as either the addition of a new medication or the deletion of an existing medication” to the end of the sentence following “with input from the Bureau Chief, has the authority to grant a change to the formulary”
Page 2, line 22	deleted “request documents” and added “information pertaining to the medication,” after “reviewing and discussing the”; changed “recommendations” to recommendation(s)”
Page 2, line 30	changed the word “re-submit” to read “resubmit “ by removing the hyphen
Page 3, lines 14-36	added a new subsection entitled “Variations of Existing Formulary Medications” and accompanying text
Page 4, line 2	deleted the entire sentence “The Program Administrator will notify the Associate Commissioner for Disease Control and Prevention and the Deputy Commissioner for Programs, of the disposition by electronic mail.”
Page 4, line 6	added “through any combination of the following methods” after “and HIV/STD contractors of the addition or deletion of a medication”
Page 4, line 8	added a new second bullet and text “by fax”
Page 4, line 11	added “email or” to the parenthetical phrase in the last bulleted statement after “via” and before “the internet if possible”
Page 4, lines 12-19	added a new section entitled “PRODUCTION AND/OR DISTRIBUTION PROBLEMS WITH EXISTING FORMULARY MEDICATIONS” and accompanying text

REQUEST TO CHANGE STATE HIV MEDICATION FORMULARY

1) **Request to (check one):** ? **ADD medication to formulary** ? **DELETE medication from formulary**	
2) **Brand name of medication:**	3) **Generic name of medication:**
4) **Will this medication replace the use of another presently on the formulary (check one):** ? **NO** ? **YES** **Which medication(s)?**	
5) **Name of pharmaceutical supply company (if single source):**	
6) **Medical criteria for using this medication:**	
7) **Other medications on the formulary that must be used in conjunction with this medication (multi-drug therapy):**	
MONTHLY CALCULATIONS	
8) **How is the medication supplied**:	9) **Maximum program supplied units per client:**
10) **Cost per unit supplied:**	11) **Estimated number of clients that will use this medication:**
FISCAL IMPACT	
12) **Present monthly expenditures:**	13) **Estimated monthly expenditure for this medication:**
14) **Estimated monthly medication expenditures with the (check one)** ? **ADDITION or** ? **DELETION of this medication:**	
15) **Maximum monthly expenditures to stay within the current budget:**	
ADVISORY COMMITTEE RECOMMENDATION	
The Committee (check one) ? **recommends /** ? **does not recommend the** ? **ADDITION /** ? **DELETION of this medication.** ? **This request is Bureau generated and was not presented to the Committee.**	
COMMISSIONER OF HEALTH APPROVAL	
Request to (check one) ? **ADD /** ? **DELETE this medication is** ? **APPROVED /** ? **DENIED.** **Signature of the Commissioner of Health:** **Date:**	

HIV/STD Form No. 700.001-A (08/00)